DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0161] (formerly Docket No. 03N–0161)

Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is adding noncompression heart stabilizers to the list of critical reprocessed single-use devices (SUDs) whose exemption from premarket notification requirements has been terminated and for which validation data, as specified under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), are necessary in a premarket notification (510(k)). The agency is also adding laparoscopic and endoscopic electrosurgical accessories to the list of reprocessed SUDs currently subject to premarket notification requirements that will now require submission of supplemental validation data. FDA is requiring submission of these data to ensure that reprocessed single-use noncompression heart stabilizers and laparoscopic and endoscopic electrosurgical accessories are substantially equivalent to predicate devices, in accordance with MDUFMA.

DATES: These actions are effective [*insert date of publication in the* **Federal Register**]. Manufacturers of reprocessed single-use noncompression heart stabilizers must submit 510(k)s for these devices by [*insert date 15 months after date of publication in the* **Federal Register**], or their devices may no

longer be legally marketed. Manufacturers of reprocessed single-use laparoscopic and endoscopic electrosurgical accessories who already have 510(k) clearance for these devices must submit supplemental validation data for the devices by [*insert date 9 months after date of publication in the* **Federal Register**], or their devices may no longer be legally marketed.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Barbara A. Zimmerman, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, ext. 158.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA (Public Law 107–250), amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 510(o) (21 U.S.C. 360(o)), which provided new regulatory requirements for reprocessed SUDs. According to this new provision, in order to ensure that reprocessed SUDs are substantially equivalent to predicate devices, 510(k)s for certain reprocessed SUDs identified by FDA must include validation data. These required validation data include cleaning and sterilization data, and functional performance data demonstrating that each SUD will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

Before enactment of the new law, a manufacturer of a reprocessed SUD was required to obtain premarket approval or premarket clearance for the device, unless the device was exempt from premarket submission requirements. Under MDUFMA, some previously exempt reprocessed SUDs are no longer exempt from premarket notification requirements. Manufacturers of these identified devices were required to submit 510(k)s that included validation data specified by FDA. Reprocessors of certain SUDs already subject to cleared 510(k)s were also required to submit the validation data specified by the agency.

The reprocessed SUDs subject to these new requirements were listed in the **Federal Register** as required by MDUFMA. In accordance with section 510(o) of the act, FDA shall revise the lists as appropriate. This notice adds two types of reprocessed SUDs to the lists of devices subject to MDUFMA's data submission requirements. Noncompression heart stabilizers are being added to the list of previously exempt reprocessed SUDs that now require the submission of 510(k)s containing validation data. Laparoscopic and endoscopic electrosurgical accessories are being added to the list of reprocessed SUDs, already subject to premarket notification requirements, for which supplemental validation data are required.

A. Definitions

Under section 302(b) of MDUFMA, a reprocessed SUD is defined as an ''original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.''

Reprocessed SUDs are divided into three groups: (1) critical, (2) semicritical, and (3) noncritical. The first two categories reflect definitions set forth in MDUFMA, and all three reflect a classification scheme recognized in the industry.[1] These categories of devices are defined as follows:

(1) *A critical reprocessed SUD* is intended to contact normally sterile tissue or body spaces during use.

(2) *A semicritical reprocessed SUD* is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

(3) *A noncritical reprocessed SUD* is intended to make topical contact and not penetrate intact skin.

B. Critical and Semicritical Reprocessed SUDs Previously Exempt From Premarket Notification

MDUFMA required FDA to review the critical and semicritical reprocessed SUDs that were previously exempt from premarket notification requirements and determine which of these devices required premarket notification to ensure their substantial equivalence to predicate devices. By April 26, 2003, FDA was required to identify in a **Federal Register** notice those critical reprocessed SUDs whose exemption from premarket notification would be terminated and for which FDA determined that validation data, as specified under MDUFMA, was necessary in a 510(k). According to the law, manufacturers of the devices whose exemptions from premarket notification were terminated were required to submit 510(k)s that included validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of a 510(k) identified in § 807.87 (21 CFR 807.87),

[1]Spaulding, E.H., ''The Role of Chemical Disinfection in the Prevention of Nonsocomial Infections,'' P.S. Brachman and T.C. Eickof (ed), Proceedings of International Conference on Nonsocomial Infections, 1970, American Hospital Association, Chicago, 254-274, 1971.

within 15 months of publication of the notice or no longer market their devices.

In accordance with section 510(o) of the act, FDA must revise the list of devices subject to this requirement as appropriate. On June 26, 2003 (68 FR 38071), FDA recategorized nine device types from semicritical to critical, and added nonelectric gastroenterology-urology biopsy forceps to the list of critical devices whose exemption from premarket notification requirements was being terminated.

By April 26, 2004, FDA was required to identify in a **Federal Register** notice those semicritical reprocessed SUDs whose exemption from premarket notification would be terminated and for which FDA determined that validation data, as specified under MDUFMA, was necessary in a 510(k). As discussed above, manufacturers of the devices whose exemptions from premarket notification were terminated were required to submit 510(k)s that included validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of a 510(k) identified in § 807.87, within 15 months of publication of the notice or no longer market their devices. In accordance with section 510(o) of the act, FDA must revise the list of devices subject to this requirement as appropriate.

C. Reprocessed SUDs Already Subject to Premarket Notification Requirements

MDUFMA also required FDA to review the types of reprocessed SUDs already subject to premarket notification requirements and to identify which of these devices required the submission of validation data to ensure their substantial equivalence to predicate devices. FDA published a list of these devices in the **Federal Register** on April 30, 2003 (68 FR 23139). As described

above, FDA must revise the list of devices subject to this requirement as appropriate.

For devices identified on this list that had already been cleared through the 510(k) process, manufacturers were required to submit validation data regarding cleaning, sterilization, and functional performance within 9 months of publication of the list or no longer market their devices.

For devices on this list that were not yet cleared through the 510(k) process, manufacturers were required to submit 510(k)s including validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements identified in 21 CFR 807.87, in order to market these devices.

II. FDA's Implementation of New Section 510(o) of the Act

In the **Federal Register** of April 30, 2003 (68 FR 23139), FDA described the methodology and criteria used to identify the reprocessed SUDs that were included in the lists required by MDUFMA. First, FDA described how it identified the types of SUDs currently being reprocessed and how the Spaulding definitions (see footnote 1) were used to categorize these devices as critical, semicritical, or noncritical. (See Attachment 1.) Next, the agency described its use of the Risk Prioritization Scheme (RPS)[2] that was used to evaluate the potential risk (high, moderate, or low) associated with an SUD based on the following factors: (1) Risk of infection and (2) risk of inadequate performance following reprocessing. FDA identified its final criterion as those reprocessed SUDs intended to come in contact with tissue at high risk of being

[2]This scheme is described in the February 2000 draft guidance document entitled, ''Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme.'' *http://www.fda.gov/cdrh/reuse/1156.html.*

infected with the causative agents of Creutzfeldt-Jakob Disease (CJD). (These are generally devices intended for use in neurosurgery and ophthalmology.)

Using this methodology and these criteria, the devices included on List I (Critical and Semicritical Reprocessed SUDs Previously Exempt from Premarket Notification Requirements that Now Require 510(k)s with Validation Data) of the April 30, 2003, June 26, 2003, and April 13, 2004, **Federal Register** notices are those critical and semicritical reprocessed SUDs that were either high risk according to the RPS or intended to come in contact with tissue at high risk of being infected with CJD. The devices included on List II (Reprocessed SUDs Subject to Premarket Notification Requirements that Now Require the Submission of Validation Data) of the April 30, 2003, **Federal Register** notice are those reprocessed SUDs already subject to premarket notification requirements that were either high risk according to the RPS or intended to come in contact with tissue at high risk of being infected with CJD.

III. Revisions to Attachment 1, List I, and List II

A. Revisions to Attachment 1 (List of SUDs Known To Be Reprocessed or Considered for Reprocessing)

FDA has evaluated the comments received regarding section 510(o) of the act. In doing so, the agency has determined that all noncompression heart stabilizers and endoscopic and laparoscopic electrosurgical accessories should be considered high risk devices when reprocessed.

Noncompression heart stabilizers are intended to move, lift, and position the heart while maintaining hemodynamic stability during cardiovascular surgery. The agency has determined that noncompression heart stabilizers are high risk devices when reprocessed because they include features, such as

narrow tubing, interlocking parts, and small crevices that could impede cleaning and sterilization and because these devices contain materials, coatings, or components that may be damaged or altered by reprocessing. Therefore, these devices have the potential for a high risk of infection and/or inadequate performance when reprocessed. This includes noncompression heart stabilizers (device 21 in Attachment 1) classified under § 870.4500 (21 CFR 870.4500). In determining that noncompression heart stabilizers are high risk devices when reprocessed, a new product code has been created to identify these devices within regulation § 870.4500. The new product code is NQG. This new product code has been added to device 21 in Attachment 1 of this document.

Endoscopic and laparoscopic electrosurgical accessories are surgical instruments used during minimally invasive surgery, including vein harvesting. The agency has determined that these devices should be considered high risk devices when reprocessed because they include features, such as narrow lumens, that could impede thorough cleaning and sterilization and because these devices contain materials, coatings, or components that may be damaged or altered by reprocessing. Therefore, these devices have the potential for a high risk of infection or inadequate performance when reprocessed. This includes endoscopic and laparoscopic electrosurgical accessories (device 162 in Attachment 1) classified under § 878.4400 (21 CFR 878.4400). In determining that endoscopic and laparoscopic electrosurgical accessories are potentially high risk devices when reprocessed, a new product code has been created to identify these devices within regulation § 878.4400. The new product code is NUJ. This new product code has been added to device 162 in Attachment 1.

These changes are reflected in a revised version of Attachment 1 included in this **Federal Register** notice.

B. Revisions to List I (Critical and Semicritical Reprocessed Single-Use Devices Previously Exempt from Premarket Notification Requirements that Now Require 510(k)s with Validation Data)

Using the RPS, FDA has recategorized noncompression heart stabilizers from moderate risk to high risk when reprocessed, and the agency has therefore added noncompression heart stabilizers to List I. Manufacturers of noncompression heart stabilizers will be required to submit 510(k)s with validation data by [*insert date 15 months after date of publication in the* **Federal Register**], which is 15 months following this revision of the list.

To help reprocessors be able to easily identify those critical and semicritical reprocessed SUDs that have been categorized into List I in this notice and previous **Federal Register** notices, FDA is re-issuing a complete listing of these devices. Therefore, List 1 now identifies all critical and semicritical reprocessed SUDs previously exempt from premarket notification requirements that now require 510(k)s with validation data.

C. Revisions to List II (Reprocessed Single-Use Devices Subject to Premarket Notification Requirements that Now Require the Submission of Validation Data)

Using the RPS, FDA has recategorized endoscopic and laparoscopic electrosurgical accessories under regulation § 878.4400 from moderate risk to high risk when reprocessed. Therefore, endoscopic and laparoscopic electrosurgical accessories have been added to List II. Under MDUFMA, manufacturers of these devices who have already obtained clearance through the 510(k) process must submit validation data regarding cleaning,

sterilization, and functional performance by [*insert date 9 months after date of publication in the* **Federal Register**], which is 9 months following this revision of the list. Upon publication of this notice, manufacturers who have not yet obtained clearance through the 510(k) process must submit 510(k)s including validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of a 510(k) identified in 21 CFR 807.87, in order to market these devices.

LIST I.—CRITICAL AND SEMICRITICAL REPROCESSED SINGLE-USE DEVICES PREVIOUSLY EXEMPT FROM PREMARKET NOTIFICATION REQUIREMENTS THAT NOW REQUIRE 510(K)S WITH VALIDATION DATA [MANUFACTURERS OF NONCOMPRESSION HEART STABILIZERS WILL NEED TO SUBMIT 510(K)S WITH VALIDATION DATA BY 15 MONTHS FOLLOWING THE PUBLICATION OF THIS REVISED LIST.]

21 CFR No.	Classification name	Product code for non-reprocessed device	Product code for re-processed device	Product code name for reprocessed device
868.6810	Tracheobronchial suction catheter	BSY	NQV	Tracheobronchial suction catheter
870.4500	Cardiovascular surgical instruments	MWS	NQG	Noncompression heart stabilizer
872.3240	Dental bur	Diamond coated	NME	Dental diamond coated bur
872.4535	Dental diamond instrument	DZP	NLD	Dental diamond instrument
872.4730	Dental injection needle	DZM	NMW	Dental needle
872.5410	Orthodontic appliance and accessories	EJF	NQS	Orthodontic metal bracket
874.4140	Ear, nose, and throat bur	Microdebrider	NLY	ENT high speed microdebrider
874.4140	Ear, nose, and throat bur	Diamond coated	NLZ	ENT diamond coated bur
874.4420	Ear, nose, throat manual surgical ..	KAB, KBG, KCI	NLB	Laryngeal, sinus, tracheal trocar
876.1075	Gastroenterology-urology biopsy instrument	FCL	NON	Nonelectric biopsy forceps
876.4680	Ureteral stone dislodger	FGO, FFL	NQT, NQU	Flexible and basket stone dislodger
878.4200	Introduction/drainage catheter and accessories	GCB	NMT	Catheter needle
878.4800	Manual surgical instrument	MJG	NNA	Percutaneous biopsy device
878.4800	Manual surgical instrument	FHR	NMU	Gastro-Urology needle
878.4800	Manual surgical instrument for	DWO	NLK	Cardiovascular biopsy needle
878.4800	Manual surgical instrument for...	GAA	NNC	Aspiration and injection needle
882.4190	Forming/cutting clip instrument	HBS	NMN	Forming/cutting clip instrument
884.1730	Laparoscopic insufflator, ..	HIF	NMI	Laparoscopic insufflator and accessories
884.4530	OB/GYN specialized manual instrument	HFB	NMG	Gynecological biopsy forceps
886.4350	Manual ophthalmic surgical instrument	HNN	NLA	Ophthalmic knife

LIST II.—REPROCESSED SINGLE-USE DEVICES SUBJECT TO PREMARKET NOTIFICATION REQUIREMENTS THAT NOW REQUIRE THE SUBMISSION OF VALIDATION DATA[1] [MANUFACTURERS OF ENDOSCOPIC AND LAPAROSCOPIC ELECTROSURGICAL ACCESSORIES WHO ALREADY HAVE 510(K) CLEARANCE FOR THESE DEVICES MUST SUBMIT VALIDATION DATA BY [*insert date 9 months after date of publication*]. Any new 510(k) for this device type will require validation data upon publication of this document.]

21 CFR No.	Classification name	Product code for nonreprocessed device	Product code for re-processed device	Product code name for reprocessed device
Unclassified	Oocyte aspiration needles	MHK	NMO	Oocyte aspiration needles

LIST II.—REPROCESSED SINGLE-USE DEVICES SUBJECT TO PREMARKET NOTIFICATION REQUIREMENTS THAT NOW REQUIRE THE SUBMISSION OF VALIDATION DATA[1] [MANUFACTURERS OF ENDOSCOPIC AND LAPAROSCOPIC ELECTROSURGICAL ACCESSORIES WHO ALREADY HAVE 510(K) CLEARANCE FOR THESE DEVICES MUST SUBMIT VALIDATION DATA BY [*insert date 9 months after date of publication*]. Any new 510(k) for this device type will require validation data upon publication of this document.]—Continued

21 CFR No.	Classification name	Product code for nonreprocessed device	Product code for reprocessed device	Product code name for reprocessed device
Unclassified	Percutaneous transluminal angioplasty catheter	LIT	NMM	Transluminal peripheral angioplasty catheter
Unclassified	Ultrasonic surgical instrument	LFL	NLQ	Ultrasonic scalpel
868.5150	Anesthesia conduction needle	BSP	NNH	Anesthetic conduction needle (with/without introducer)
868.5150	Anesthesia conduction needle	MIA	NMR	Short term spinal needle
868.5730	Tracheal tube	BTR	NMA	Tracheal tube (with/without connector)
868.5905	Noncontinuous ventilator (IPPB)	BZD	NMC	Noncontinuous ventilator (respirator) mask
870.1200	Diagnostic intravascular catheter	DQO	NLI	Angiography catheter
870.1220	Electrode Recording Catheter	DRF	NLH	Electrode recording catheter
870.1220	Electrode Recording Catheter	MTD	NLG	Intracardiac mapping catheter
870.1230	Fiberoptic oximeter catheter	DQE	NMB	Fiberoptic oximeter catheter
870.1280	Steerable Catheter	DRA	NKS	Steerable Catheter
870.1290	Steerable catheter control system	DXX	NKR	Steerable catheter control system
870.1330	Catheter guide wire	DQX	NKQ	Catheter guide wire
870.1390	Trocar	DRC	NMK	Cardiovascular trocar
870.1650	Angiographic injector and syringe	DXT	NKT	Angiographic injector and syringe
870.1670	Syringe actuator for injector	DQF	NKW	Injector for actuator syringe
870.2700	Oximeter	MUD	NMD	Tissue saturation oximeter
870.2700	Oximeter	DQA	NLF	Oximeter
870.3535	Intra-aortic balloon and control system	DSP	NKO	Intra-aortic balloon and control system
870.4450	Vascular clamp	DXC	NMF	Vascular clamp
870.4885	External vein stripper	DWQ	NLJ	External vein stripper
872.5470	Orthodontic Plastic Bracket	DYW	NLC	Orthodontic Plastic Bracket
874.4680	Bronchoscope (flexible or rigid) and accessories	BWH	NLE	Bronchoscope (nonrigid) biopsy forceps
876.1075	Gastro-Urology biopsy instrument	FCG	NMX	G-U biopsy needle and needle set
876.1075	Gastroenterology-urology biopsy instrument	KNW	NLS	Biopsy instrument
876.1500	Endoscope and accessories	FBK, FHP	NMY	Endoscopic needle
876.1500	Endoscope and accessories	MPA	NKZ	Endoilluminator
876.1500	Endoscope and accessories	GCJ	NLM	General and plastic surgery laparoscope
876.1500	Endoscope and accessories	FHO	NLX	Spring-loaded pneumoperitoneum needle
876.4300	Endoscopic electrosurgical unit and accessories	FAS	NLW	Active Urological electrosurgical electrode
876.4300	Endoscopic electrosurgical unit and accessories	FEH	NLV	Flexible suction coagulator electrode
876.4300	Endoscopic electrosurgical unit and accessories	KGE	NLU	Electric biopsy forceps
876.4300	Endoscopic electrosurgical unit and accessories	FDI	NLT	Flexible snare
876.4300	Endoscopic electrosurgical unit and accessories	KNS	NLR	Endoscopic (with or without accessories) Electrosurgical unit

LIST II.—REPROCESSED SINGLE-USE DEVICES SUBJECT TO PREMARKET NOTIFICATION REQUIREMENTS THAT NOW REQUIRE THE SUBMISSION OF VALIDATION DATA[1] [MANUFACTURERS OF ENDOSCOPIC AND LAPAROSCOPIC ELECTROSURGICAL ACCESSORIES WHO ALREADY HAVE 510(K) CLEARANCE FOR THESE DEVICES MUST SUBMIT VALIDATION DATA BY [*insert date 9 months after date of publication*]. Any new 510(k) for this device type will require validation data upon publication of this document.]—Continued

21 CFR No.	Classification name	Product code for nonreprocessed device	Product code for reprocessed device	Product code name for reprocessed device
876.5010	Biliary catheter and accessories	FGE	NML	Biliary catheter
876.5540	Blood access device and accessories	LBW	NNF	Single needle dialysis set (co-axial flow)
876.5540	Blood access device and accessories	FIE	NNE	Fistula needle
876.5820	Hemodialysis systems and accessories	FIF	NNG	Single needle dialysis set with uni-directional pump
878.4300	Implantable clip	FZP	NMJ	Implantable clip
878.4400	Electrosurgical Cutting and Coagulation Device and Accessories	GEI	NUJ	Endoscopic and laparoscopic electrosurgical accessories
878.4750	Implantable staple	GDW	NLL	Implantable staple
880.5570	Hypodermic single lumen needle	FMI	NKK	Hypodermic single lumen needle
880.5860	Piston Syringe	FMF	NKN	Piston Syringe
882.4300	Manual cranial drills, burrs, trephines and accessories	HBG	NLO	(Manual) drills, burrs, trephines and accessories
882.4305	Powered compound cranial drills, burrs, trephines .	HBF	NLP	(Powered, compound) drills, burrs, trephines and accessories
882.4310	Powered simple cranial drills, burrs, trephines .	HBE	NLN	(Simple, powered) drills, burrs, trephines and accessories
884.1720	Gynecologic laparoscope and accessories	HET	NMH	Gynecologic laparoscope (and accessories)
884.6100	Assisted reproduction needle	MQE	NNB	Assisted reproduction needle
886.4370	Keratome	HMY, HNO	NKY	Keratome blade
886.4670	Phacofragmentation system	HQC	NKX	Phacoemulsification needle
892.5730	Radionuclide brachytherapy source	IWF	NMP	Isotope needle

[1]Hemodialyzers have been excluded from this list because the reuse of hemodialyzers is addressed in ''Draft Guidance for Hemodialyzer Reuse Labeling'' October 6, 1995. An archived copy may be obtained from CDRH's Division of Small Manufacturers, International, and Consumer Assistance, please contact *dsmica@cdrh.fda.gov*.

III. Stakeholder Input

In the **Federal Register** of February 4, 2003 (68 FR 5643), FDA invited interested persons to provide information and share views on the implementation of MDUFMA. Since that time, the agency has received comments on various MDUFMA provisions, including several on its implementation of section 510(o) of the act. As discussed above, one comment recommended that heart stabilizers should be considered high risk because of the risk of cross contamination and deterioration of the mechanical properties of the device. FDA agrees that noncompression heart stabilizers, a subset of all heart stabilizers, should be added to the list of critical reprocessed SUDs

previously exempt from premarket notification requirements that will now require 510(k)s with validation data. Therefore, FDA has added noncompression heart stabilizers to List I.

Another comment recommended that FDA recategorize endoscopic vessel harvesting devices as high risk to be consistent with the categorization of other endoscopic accessories under 21 CFR 876.1500 (Endoscope and accessories). FDA agrees that endoscopic vessel harvesting devices should be considered high risk and subject to the submission of validation data. As discussed previously, in reviewing this comment, the agency also determined that laparoscopic electrosurgical accessories should be similarly categorized. Therefore, FDA has added laparoscopic and endoscopic electrosurgical accessories to List II.

Other additional comments requested that specific reprocessed SUDs be added to either List I or II. Each of these comments was carefully considered. However, FDA does not believe, based on the risk-based approach described in the April 30, 2003, **Federal Register** notice, that SUDs other than those identified in this notice should be added to the Lists at this time.

Another comment requested the FDA to call for the immediate submission and review of validation data regarding cleaning, sterilization, and functional performance for all reprocessed SUDs. The comment further stated that this request was based on the significant number of reprocessed devices which were withdrawn or were deemed to be insufficiently supported by validation data as of February 8, 2005.

Section 510(o) of the act required FDA to identify those reprocessed SUDs for which validation data must be submitted in order to ensure that those SUDs remain substantially equivalent to predicate devices after reprocessing.

Because the agency has found that some reprocessed SUDs do not require the submission and review of validation data in order to demonstrate substantial equivalence, the agency identified the types of devices requiring the submission of validation data by implementing a risk-based approach. This risk-based approach, described in the April 30, 2003, **Federal Register** notice, identified a significant number of reprocessed SUDs that can no longer be legally marketed without agency review and clearance of validation data. The failure of some manufacturers to submit this validation data and the agency's review of submitted data resulted in a determination that a significant number of reprocessed SUDs could no longer be legally marketed. However, the process also identified a significant number of reprocessed SUDs that could continue to be marketed because: (1) they were found not to require the submission of additional validation data in order to ensure substantial equivalence to legally marketed predicate devices; or (2) after a review of submitted validation data, they were found to be substantially equivalent to legally marketed predicate devices. Therefore, FDA does not intend to expand the list of reprocessed SUDs subject to the submission and review of validation data to all reprocessed SUDs as requested in the comment. The agency believes it has implemented section 510(o) of the act by identifying the types of devices that require the submission of validation data and determining which of those devices can no longer be legally marketed.

IV. Comments

You may submit written or electronic comments on the designation of reprocessed noncompression heart stabilizers and laparoscopic and endoscopic electrosurgical devices requiring the submission of premarket notifications with validation data to the Division of Dockets Management (see **ADDRESSES**).

Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Submit two copies of mailed comments, but individuals may submit one copy. You should identify your comments with the docket number found in brackets in the heading of this document. You may see any comments FDA receives in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Attachment 1 List of SUDs Known To Be Reprocessed or Considered for Reprocessing

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk[A]	Critical/Semicritical/ Noncritical	Premarket Exempt
1	Cardio	Cardiopulmonary Bypass Marker	Unclassified		MAB	1	C	N
2	Cardio	Percutaneous & Operative Transluminal Coronary Angioplasty Catheter (PTCA)	Post-amend-ment	III	LOX	3	C	N
3	Cardio	Percutaneous Ablation Electrode	Post-amend-ment	III	LPB	3	C	N
4	Cardio	Peripheral Transluminal Angioplasty (PTA) Catheter	870.1250	II	LIT	3	C	N
5	Cardio	Blood-Pressure Cuff	870.1120	II	DXQ	1	N	N
6	Cardio	Angiography Catheter	870.1200	II	DQO	3	C	N
7	Cardio	Electrode Recording Catheter	870.1220	II	DRF	3	C	N
8	Cardio	High-Density Array Catheter	870.1220	II	MTD	3	C	N
9	Cardio	Fiberoptic Oximeter Catheter	870.1230	II	DQE	3	C	N
10	Cardio	Steerable Catheter	870.1280	II	DRA	3	C	N
11	Cardio	Steerable Catheter Control Sys-tem	870.1290	II	DXX	3	C	N
12	Cardio	Guide Wire	870.1330	II	DQX	3	C	N
13	Cardio	Angiographic Needle	870.1390	II	DRC	3	C	N
14	Cardio	Trocar	870.1390	II	DRC	3	C	N
15	Cardio	Syringes	870.1650	II	DXT	3	C	N
16	Cardio	Injector Type Syringe Actuator	870.1670	II	DQF	3	C	N
17	Cardio	Oximeter	870.2700	II	DQA	3	N	N
18	Cardio	Tissue Saturation Oximeter	870.2700	II	MUD	3	C	N
19	Cardio	Intra-Aortic Balloon System	870.3535	III	DSP	3	C	N
20	Cardio	Vascular Clamp	870.4450	II	DXC	3	C	N
21	Cardio	Heart Stabilizer	870.4500	I	MWS	2	C	Y
22	Cardio	Noncompression Heart Stabilizer	870.4500	I	MWS	3	C	Y
23	Cardio	External Vein Stripper	870.4885	II	DWQ	3	C	N
24	Cardio	Compressible Limb Sleeve	870.5800	II	JOW	1	N	N
25	Dental	Bur	872.3240	I	EJL	1	C	Y
26	Dental	Diamond Coated Bur	872.3240	I	EJL	3	C	Y
27	Dental	Diamond Instrument	872.4535	I	DZP	3	C	Y
28	Dental	AC-Powered Bone Saw	872.4120	II	DZH	2	C	N

Attachment 1 List of SUDs Known To Be Reprocessed or Considered for Reprocessing—Continued

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk[A]	Critical/Semicritical/ Noncritical	Premarket Exempt
29	Dental	Manual Bone Drill and Wire Driver	872.4120	II	DZJ	2	C	N
30	Dental	Powered Bone Drill	872.4120	II	DZI	2	C	N
31	Dental	Intraoral Drill	872.4130	I	DZA	1	C	Y
32	Dental	Injection needle	872.4730	I	DZM	3	C	Y
33	Dental	Metal Orthodontic Bracket	872.5410	I	EJF	3	S	Y
34	Dental	Plastic Orthodontic Bracket	872.5470	II	DYW	3	S	N
35	ENT	Bur	874.4140	I	EQJ	1	C	Y
36	ENT	Diamond Coated Bur	874.4140	I	EQJ	3	C	Y
37	ENT	Microdebrider	874.4140	I	EQJ	3	C	Y
38	ENT	Microsurgical Argon Fiber Optic Laser Cable, For Uses Other Than Otology, Including Laryngology & General Use In Otolaryngology	874.4490	II	LMS	1	S	N
39	ENT	Microsurgical Argon Fiber Optic Laser Cable, For Use In Otology	874.4490	II	LXR	1	S	N
40	ENT	Microsurgical Carbon-Dioxide Fiber Optic Laser Cable	874.4500	II	EWG	1	S	N
41	ENT	Bronchoscope Biopsy Forceps (Nonrigid)	874.4680	II	BWH	3	C	N
42	ENT	Bronchoscope Biopsy Forceps (Rigid)	874.4680	II	JEK	1	C	N
43	Gastro/ Urology	Biopsy Forceps Cover	876.1075	I	FFF	1	C	Y
44	Gastro/ Urology	Biopsy Instrument	876.1075	II	KNW	3	C	N
45	Gastro/ Urology	Biopsy Needle Set	876.1075	II	FCG	3	C	N
46	Gastro/ Urology	Biopsy Punch	876.1075	II	FCI	2	C	N
47	Gastro/ Urology	Mechanical Biopsy Instrument	876.1075	II	FCF	2	C	N
48	Gastro/ Urology	Nonelectric Biopsy Forceps	876.1075	I	FCL	3	C	Y
49	Gastro/ Urology	Cytology Brush For Endoscope	876.1500	II	FDX	2	S	N
50	Gastro/ Urology	Endoscope accessories	876.1500	II	KOG	2	S	N
51	Gastro/ Urology	Extraction Balloons/Baskets	876.1500	II	KOG	2	S	N
52	Gastro/Urology	Endoscopic needle	876.1500	II	FBK	3	C	N
53	Gastro/ Urology	Simple Pneumoperitoneum Needle	876.1500	II	FHP	3	C	N
54	Gastro/ Urology	Spring Loaded Pneumoperitoneum Needle	876.1500	II	FHO	3	C	N
55	Gastro/ Urology	Active Electrosurgical Electrode	876.4300	II	FAS	3	S	N
56	Gastro/ Urology	Biliary Sphincterotomes	876.5010, 876.1500	II	FGE	3	C	N

Attachment 1 List of SUDs Known To Be Reprocessed or Considered for Reprocessing—Continued

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk[A]	Critical/Semicritical/ Noncritical	Premarket Exempt
57	Gastro/ Urology	Electric Biopsy Forceps	876.4300	II	KGE	3	C	N
58	Gastro/ Urology	Electrosurgical Endoscopic Unit (With Or Without Accessories)	876.4300	II	KNS	3	S	N
59	Gastro/ Urology	Flexible Snare	876.4300	II	FDI	3	S	N
60	Gastro/ Urology	Flexible Suction Coagulator Electrode	876.4300	II	FEH	3	S	N
61	Gastro/ Urology	Flexible Stone Dislodger	876.4680	II	FGO	3	S	Y
62	Gastro/ Urology	Metal Stone Dislodger	876.4680	II	FFL	3	S	Y
63	Gastro/ Urology	Needle Holder	876.4730	I	FHQ	1	C	Y
64	Gastro/ Urology	Nonelectrical Snare	876.4730	I	FGX	1	S	Y
65	Gastro/ Urology	Urological Catheter	876.5130	II	KOD	2	S	N
66	Gastro/Urology	Single needle dialysis set	876.5540	II	LBW, FIE	3	C	N
67	Gastro/ Urology	Hemodialysis Blood Circuit Accessories	876.5820	II	KOC	2	S	N
68	Gastro/Urology	Single needle dialysis set	876.5820	II	FIF	3	C	N
69	Gastro/Urology	Hemorrhoidal Ligator	876.4400	II	FHN	2	C	N
70	General Hospital	Implanted, Programmable Infusion Pump	Post-amendment	III	LKK	3	C	N
71	General Hospital	Needle Destruction Device	Post-amendment	III	MTV	1	N	N
72	General Hospital	Nonpowered Flotation Therapy Mattress	880.5150	I	IKY	2	N	Y
73	General Hospital	NonAC-Powered Patient Lift	880.5510	I	FSA	2	N	Y
74	General Hospital	Alternating Pressure Air Flotation Mattress	880.5550	II	FNM	1	N	Y
75	General Hospital	Temperature Regulated Water Mattress	880.5560	I	FOH	2	N	Y
76	General Hospital	Hypodermic Single Lumen Needle	880.5570	II	FMI	3	C	N
77	General Hospital	Piston Syringe	880.5860	II	FMF	3	C	N
78	General Hospital	Mattress Cover (Medical Purposes)	880.6190	I	FMW	2	N	Y
79	General Hospital	Disposable Medical Scissors	880.6820	I	JOK	1	N	Y
80	General Hospital	Irrigating Syringe	880.6960	I	KYZ, KYY	1	C	Y
81	Infection Control	Surgical Gowns	878.4040	II	FYA	1	C	N
82	Lab	Blood Lancet	878.4800	I	FMK	1	C	Y
83	Neurology	Clip Forming/Cutting Instrument,	882.4190	I	HBS	3*	C	Y
84	Neurology	Drills, Burrs, Trephines &Accessories (Manual)	882.4300	II	HBG	3*	C	N

Attachment 1 List of SUDs Known To Be Reprocessed or Considered for Reprocessing—Continued

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk[A]	Critical/Semicritical/ Noncritical	Premarket Exempt
85	Neurology	Drills, Burrs, Trephines &Accessories (Compound, Powered)	882.4305	II	HBF	3*	C	N
86	Neurology	Drills, Burrs, Trephines &Accessories (Simple, Powered)	882.4310	II	HBE	3*	C	N
87	OB/GYN	Oocyte aspiration needle		III	MHK	3	C	N
88	OB/GYN	Laparoscope accessories	884.1720	I	HET	2	C	Y
89	OB/GYN	Laparoscope Accessories	884.1720	II	HET	3	C	N
90	OB/GYN	Laparoscopic Dissectors	884.1720	I	HET	2	C	Y
91	OB/GYN	Laparoscopic Graspers	884.1720	I	HET	2	C	Y
92	OB/GYN	Laparoscopic Scissors	884.1720	I	HET	2	C	Y
93	OB/GYN	Insufflator accessories (tubing, Verres needle, kits)	884.1730	II	HIF	3	C	Y
94	OB/GYN	Laparoscopic Insufflator	884.1730	II	HIF	2	N	N
95	OB/GYN	Endoscopic Electrocautery and Accessories	884.4100	II	HIM	2	N	N
96	OB/GYN	Gynecologic Electrocautery (and Accessories)	884.4120	II	HGI	2	N	N
97	OB/GYN	Endoscopic Bipolar Coagulator-Cutter (and Accessories)	884.4150	II	HIN	2	N	N
98	OB/GYN	Culdoscopic Coagulator (and Accessories)	884.4160	II	HFI	2	N	N
99	OB/GYN	Endoscopic Unipolar Coagulator-Cutter (and Accessories)	884.4160	II	KNF	2	N	N
100	OB/GYN	Hysteroscopic Coagulator (and Accessories)	884.4160	II	HFH	2	N	N
101	OB/GYN	Unipolar Laparoscopic Coagulator (and Accessories)	884.4160	II	HFG	2	N	N
102	OB/GYN	Episiotomy Scissors	884.4520	I	HDK	1	C	Y
103	OB/GYN	Umbilical Scissors	884.4520	I	HDJ	1	C	Y
104	OB/GYN	Biopsy Forceps	884.4530	I	HFB	3	C	Y
105	OB/GYN	Assisted reproduction needle	884.6100	II	MQE	3	C	N
106	Ophthalmic	Endoilluminator	876.1500	II	MPA	3*	C	N
107	Ophthalmic	Surgical Drapes	878.4370	II	KKX	2	C	N
108	Ophthalmic	Ophthalmic Knife	886.4350	I	HNN	3	C	Y
109	Ophthalmic	Keratome Blade	886.4370	I	HMY, HNO	3	C	N
110	Ophthalmic	Phacoemulsification Needle	886.4670	II	HQC	3	C	N
111	Ophthalmic	Phacoemulsification/ Phacofragmentation Fluidic	886.4670	II	MUS	2	C	N
112	Ophthalmic	Phacofragmentation Unit	886.4670	II	HQC	1	N	N
113	Orthopedic	Saw Blades	878.4820	I	GFA, DWH, GEY, GET	1	C	Y
114	Orthopedic	Surgical Drills	878.4820	I	GEY, GET	1	C	Y
115	Orthopedic	Arthroscope accessories	888.1100	II	HRX	2	C	Y
116	Orthopedic	Bone Tap	888.4540	I	HWX	1	C	Y
117	Orthopedic	Burr	888.4540	I	HTT	1	C	Y

Attachment 1 List of SUDs Known To Be Reprocessed or Considered for Reprocessing—Continued

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk[A]	Critical/Semicritical/ Noncritical	Premarket Exempt
118	Orthopedic	Carpal Tunnel Blade	888.4540	I	LXH	2	C	Y
119	Orthopedic	Countersink	888.4540	I	HWW	1	C	Y
120	Orthopedic	Drill Bit	888.4540	I	HTW	1	C	Y
121	Orthopedic	Knife	888.4540	I	HTS	1	C	Y
122	Orthopedic	Manual Surgical Instrument	888.4540	I	LXH	1	C	Y
123	Orthopedic	Needle Holder	888.4540	I	HXK	1	C	Y
124	Orthopedic	Reamer	888.4540	I	HTO	1	C	Y
125	Orthopedic	Rongeur	888.4540	I	HTX	1	C	Y
126	Orthopedic	Scissors	888.4540	I	HRR	1	C	Y
127	Orthopedic	Staple Driver	888.4540	I	HXJ	1	C	Y
128	Orthopedic	Trephine	888.4540	I	HWK	1	C	Y
129	Orthopedic	Flexible Reamers/Drills	886.4070 878.4820	I	GEY, HRG	1	C	Y
130	Orthopedic	External Fixation Frame	888.3040 888.3030	II	JEC KTW KTT	2	N	N
131	Physical Medicine	Nonheating Lamp for Adjunctive Use Inpatient Therapy	890.5500	II	NHN	1	N	N
132	Physical Medicine	Electrode Cable,	890.1175	II	IKD	1	N	Y
133	Physical Medicine	External Limb Component, Hip Joint	890.3420	I	ISL	2	N	Y
134	Physical Medicine	External Limb Component, Knee Joint	890.3420	I	ISY	2	N	Y
135	Physical Medicine	External Limb Component, Mechanical Wrist	890.3420	I	ISZ	2	N	Y
136	Physical Medicine	External Limb Component, Shoulder Joint	890.3420	I	IQQ	2	N	Y
137	Plastic Surgery	Stapler	878.4800	I	GAG, GEF, FHM, HBT	2	C	Y
138	Radiology	Isotope Needle	892.5730	II	IWF	3	C	N
139	Respiratory	Endotracheal Tube Changer	Unclassified	III	LNZ	3	C	N
140	Respiratory	Anesthesia conduction needle	868.5150	II	BSP	3	C	N
141	Respiratory	Short term spinal needle	868.5150	II	MIA	3	C	N
142	Respiratory	Respiratory Therapy and Anesthesia Breathing Circuits	868.5240	I	CAI	2	S	Y
143	Respiratory	Oral and Nasal Catheters	868.5350	I	BZB	1	C	Y
144	Respiratory	Gas Masks	868.5550	I	BSJ	1	S	Y
145	Respiratory	Breathing Mouthpiece	868.5620	I	BYP	1	N	Y
146	Respiratory	Tracheal Tube	868.5730	II	BTR	3	C	N
147	Respiratory	Airway Connector	868.5810	I	BZA	2	S	Y
148	Respiratory	CPAP Mask	868.5905	II	BZD	3	S	N
149	Respiratory	Emergency Manual Resuscitator	868.5915	II	BTM	2	S	N
150	Respiratory	Tracheobronchial Suction Catheter	868.6810	I	BSY	3	S	Y
151	Surgery	AC-powered Orthopedic Instrument and accessories	878.4820	I	HWE	2	C	N

Attachment 1 List of SUDs Known To Be Reprocessed or Considered for Reprocessing—Continued

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk[A]	Critical/Semicritical/ Noncritical	Premarket Exempt
152	Surgery	Breast Implant Mammary Sizer	Unclassified		MRD	1	C	N
153	Surgery	Ultrasonic Surgical Instrument	Unclassified		LFL	3	C	N
154	Surgery	Trocar	874.4420	I	KAB, KBG, KCI	3	C	Y
155	Surgery	Endoscopic Blades	876.1500	II	GCP, GCR	2	C	N
156	Surgery	Endoscopic Guidewires	876.1500	II	GCP, GCR	1	C	N
157	Surgery	Inflatable External Extremity Splint	878.3900	I	FZF	1	N	Y
158	Surgery	Noninflatable External Extremity Splint	878.3910	I	FYH	1	N	Y
159	Surgery	Catheter needle	878.4200	I	GCB	3	C	Y
160	Surgery	Implantable Clip	878.4300	II	FZP	3	C	N
161	Surgery	Electrosurgical and Coagulation Unit With Accessories	878.4400	II	BWA	2	C	N
162	Surgery	Electrosurgical Apparatus	878.4400	II	HAM	2	C	N
163	Surgery	Electrosurgical Cutting & Coagulation Device & Accessories	878.4400	II	GEI NUJ	2 3	C	N
164	Surgery	Electrosurgical Device	878.4400	II	DWG	2	C	N
165	Surgery	Electrosurgical Electrode	878.4400	II	JOS	2	C	N
166	Surgery	Implantable Staple, Clamp, Clip for Suturing Apparatus	878.4750	II	GDW	3	C	N
167	Surgery	Percutaneous biopsy device	878.4800	I	MJG	3	C	Y
168	Surgery	Gastro-Urology needle	878.4800	I	FHR	3	C	Y
169	Surgery	Aspiration and injection needle	878.4800	I	GAA	3	C	Y
170	Surgery	Biopsy Brush	878.4800	I	GEE	1	C	Y
171	Surgery	Blood Lancet	878.4800	I	FMK	1	C	Y
172	Surgery	Bone Hook	878.4800	I	KIK	1	C	Y
173	Surgery	Cardiovascular Biopsy Needle	878.4800	I	DWO	3	C	Y
174	Surgery	Clamp	878.4800	I	GDJ	1	C	Y
175	Surgery	Clamp	878.4800	I	HXD	1	C	Y
176	Surgery	Curette	878.4800	I	HTF	1	C	Y
177	Surgery	Disposable Surgical Instrument	878.4800	I	KDC	1	C	Y
178	Surgery	Disposable Vein Stripper	878.4800	I	GAJ	1	C	Y
179	Surgery	Dissector	878.4800	I	GDI	1	C	Y
180	Surgery	Forceps	878.4800	I	GEN	2	C	Y
181	Surgery	Forceps	878.4800	I	HTD	2	C	Y
182	Surgery	Gouge	878.4800	I	GDH	1	C	Y
183	Surgery	Hemostatic Clip Applier	878.4800	I	HBT	2	C	Y
184	Surgery	Hook	878.4800	I	GDG	1	C	Y
185	Surgery	Manual Instrument	878.4800	I	MDM, MDW	1	C	Y
186	Surgery	Manual Retractor	878.4800	I	GZW	1	C	Y
187	Surgery	Manual Saw and Accessories	878.4800	I	GDR HAC	1	C	Y
188	Surgery	Manual Saw and Accessories	878.4800	I	HAC	1	C	Y

Attachment 1 List of SUDs Known To Be Reprocessed or Considered for Reprocessing—Continued

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk[A]	Critical/Semicritical/ Noncritical	Premarket Exempt
189	Surgery	Manual Surgical Chisel	878.4800	I	FZO	1	C	Y
190	Surgery	Mastoid Chisel	878.4800	I	JYD	1	C	Y
191	Surgery	Orthopedic Cutting Instrument	878.4800	I	HTZ	1	C	Y
192	Surgery	Orthopedic Spatula	878.4800	I	HXR	1	C	Y
193	Surgery	Osteotome	878.4800	I	HWM	1	C	Y
194	Surgery	Rasp	878.4800	I	GAC	1	C	Y
195	Surgery	Rasp	878.4800	I	HTR	1	C	Y
196	Surgery	Retractor	878.4800	I	GAD	1	C	Y
197	Surgery	Retractor	878.4800	I	HXM	1	C	Y
198	Surgery	Saw	878.4800	I	HSO	1	C	Y
199	Surgery	Scalpel Blade	878.4800	I	GES	1	C	Y
200	Surgery	Scalpel Handle	878.4800	I	GDZ	1	C	Y
201	Surgery	Scissors	878.4800	I	LRW	1	C	Y
202	Surgery	Snare	878.4800	I	GAE	1	C	Y
203	Surgery	Spatula	878.4800	I	GAF	1	C	Y
204	Surgery	Staple Applier	878.4800	I	GEF	2	C	Y
205	Surgery	Stapler	878.4800	I	GAG	2	C	Y
206	Surgery	Stomach and Intestinal Suturing Apparatus	878.4800	I	FHM	2	C	Y
207	Surgery	Surgical Curette	878.4800	I	FZS	1	C	Y
208	Surgery	Surgical Cutter	878.4800	I	FZT	1	C	Y
209	Surgery	Surgical Knife	878.4800	I	EMF	1	S	Y
210	Surgery	Laser Powered Instrument	878.4810	II	GEX	2	C	N
211	Surgery	AC-Powered Motor	878.4820	I	GEY	2	C	Y
212	Surgery	Bit	878.4820	I	GFG	1	C	Y
213	Surgery	Bur	878.4820	I	GFF, GEY	1	C	Y
214	Surgery	Cardiovascular Surgical Saw Blade	878.4820	I	DWH	1	C	Y
215	Surgery	Chisel (Osteotome)	878.4820	I	KDG	1	C	Y
216	Surgery	Dermatome	878.4820	I	GFD	1	C	Y
217	Surgery	Electrically Powered Saw	878.4820	I	DWI	2	C	Y
218	Surgery	Pneumatic Powered Motor	878.4820	I	GET	2	C	Y
219	Surgery	Pneumatically Powered Saw	878.4820	I	KFK	2	C	Y
220	Surgery	Powered Saw and Accessories	878.4820	I	HAB	2	C	Y
221	Surgery	Saw Blade	878.4820	I	GFA	1	C	Y
222	Surgery	Nonpneumatic Tourniquet	878.5900	I	GAX	1	N	Y
223	Surgery	Pneumatic Tourniquet	878.5910	I	KCY	1	N	Y
224	Surgery	Endoscopic Staplers	888.4540	I	HXJ	2	C	Y
225	Surgery	Trocar	876.1500 870.1390	II	GCJ, DRC	3	C	N
226	Surgery	Surgical Cutting Accessories	878.4800, 874.4420	I	GDZ, GDX, GES, KBQ, KAS	2	C	Y

Attachment 1 List of SUDs Known To Be Reprocessed or Considered for Reprocessing—Continued

	Medical Specialty	Device Type	Regulation Number	Class	Product Code	Risk[A]	Critical/Semicritical/ Noncritical	Premarket Exempt
227	Surgery	Electrosurgical Electrodes/Handles/Pencils	876.4300 878.4400	II	HAM, GEI, FAS	2	C	N
228	Surgery	Scissor Tips	878.4800, 884.4520, 874.4420	I	LRW, HDK, HDJ, JZB, KBD	2	C	Y
229	Surgery	Laser Fiber Delivery Systems	878.4810 874.4500 886.4390 884.4550 886.4690	II	GEX EWG LLW HQF HHR HQB	1	C	N

[A]Risk categorization may be either:
1 = low risk according to RPS
2 = moderate risk according to RPS
3 = high risk according to RPS
3* = high risk due to neurological use
See section II of this document, ''FDA's Implementation of New Section 510(o) of the Act'' for methodology and criteria used to identify the risk.

Dated: September 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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